

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in this application:

Listing of claims:

1. (Currently Amended) A process for preparing a fine particulate protein substance or substance mixture ~~substances or mixtures thereof~~, said fine particulate protein substance or substance mixture having a particle size in the nanometer to micrometer ~~the nano (nm) to micrometer (μm)~~ range, ~~which said process~~ comprises:

grinding a protein ~~the substance or substance mixture~~ at a low temperature in a suspending medium ~~in which said substance or mixture is substantially insoluble~~, said low temperature being lower than -30°C., wherein said suspending medium is gaseous at ambient pressure and temperature;
and

removing said suspending medium.

2. (Currently Amended) The process of claim 1, wherein said suspending medium is an unsubstituted hydrocarbon, a hydrocarbon mono-or -polysubstituted by fluorine, a mixture ~~or mixtures thereof~~.

3. (Currently Amended) The process of claim 1, wherein said suspending medium is a hydrocarbon mono- or -polysubstituted by fluorine, selected from ~~one or more~~ the group consisting of TG227, TG134a, TG152a, TG143a, and mixtures thereof.

4. (Currently Amended) The process of claim 1, wherein said suspending medium is an unsubstituted hydrocarbon ~~which is at least one of~~ selected from the group consisting of butane, isobutane, pentane, hexane, ~~and heptane~~ and mixtures thereof.

5. (Currently Amended) The process of claim 1, wherein said suspending medium is ~~at least one of~~ selected from the group consisting of isobutane, pentane, hexane, heptane, TG227, TG134a, TG152a, ~~and~~ TG143a and mixtures thereof.

6. (Currently Amended) The process of claim 1, wherein said low temperature is $\leq 30^{\circ}\text{C}$, lower than -40°C , $\leq 50^{\circ}\text{C}$. or $\leq 60^{\circ}\text{C}$.

7. (Currently Amended) The process of claim 1, further comprising adding ~~wherein~~
~~before or after grinding the protein or protein mixture substance~~ an excipient to said
suspending medium ~~is added to the mixture~~ before or after grinding said protein substance or
substance mixture, said excipient being selected from the group consisting of ~~one or more of~~
lactose, dextrose, sorbitol, mannitol, polyalcohols ~~a polyol~~, xylitol, disaccharides,
polysaccharides, and oligosaccharides, dextrans, amino acids, solid lipids, solid phospholipids,
vitamins, surfactants, polymers and mixtures thereof.

8. (Currently Amended) The process of claim 1, wherein said protein substance ~~the~~
~~protein or protein mixture to be ground~~, is abarelix, buserelin ~~buserelix~~, cetorelix, leuprolide,
cyclosporine, ganirelix, glucagon, lutropin-~~(LH)~~, insulin, ramorelix, or teverelix-~~(Antarelix)~~.

9. (Currently Amended) A solid, fine-particulate pharmaceutical preparation for
inhalatory administration to mammals, which comprises a fine particulate protein substance or
substance mixture ~~at least one active compound for inhalatory administration in mammals, when~~
obtained by the process of claim 1.

10. (Currently Amended) The solid, fine-particulate pharmaceutical preparation of
claim 9, wherein said active compound is abarelix, buserelin ~~buserelix~~, cetorelix, leuprolide,
cyclosporine, ganirelix, glucagon, lutropin-~~(LH)~~, insulin, ramorelix, or teverelix-~~(Antarelix)~~.

11. (Original) The solid, fine-particulate pharmaceutical preparation of claim 9 when
filled into a powder inhaler.

12. (Currently Amended) The solid, fine-particulate pharmaceutical preparation of claim
11 ~~9~~, wherein said powder inhaler is DPI, MDPI or a blister inhaler.

13. (Currently Amended) A process for applying a fine-particulate substance or substance mixture to a carrier material, which comprises stripping off by thorough mixing the suspending medium from a suspension of said fine particulate substance or substance mixture, said carrier material and said substance or substance mixture being substantially insoluble in said suspending medium.

14. (Canceled)

15. (Currently Amended) The process of claim 13, wherein said suspending medium is selected from the group consisting one or more of unsubstituted hydrocarbons, and of hydrocarbons mono- or polysubstituted by fluorine, and mixtures thereof.

16. (Currently Amended) The process of claim 13, wherein said suspending medium is selected from the group consisting one or more of isobutane, pentane, hexane, heptane, TG227, TG134a, TG152a, and TG143a and mixtures thereof.

17. (Currently Amended) The process of claim 13, wherein said carrier material is selected from the group consisting one or more of a spherical lactose having a smooth surface, and an agglomerated lactose having a rough surface, and mixtures thereof.

18. (Currently Amended) The process of claim 13, wherein said fine particulate substance or substance mixture has an average particle size of ~~of~~ from about 0.1 to about 10 μm , and said carrier material has an average particle particle size of from about 10 to about 900 μm .

19. (Currently Amended) The process of claim 13, wherein said ~~suspending~~suspending medium further contains an excipient selected from the group consisting which is one or more of lactose, dextrose, sorbitol, mannitol, polyalcohols a polyol, xylitol, disaccharides, polysaccharides, ~~and oligosaccharides~~, dextrans, amino acids, solid lipids, solid phospholipids, vitamins, surfactants, ~~and polymers~~ and mixtures thereof.

20. (New) The process of claim 1, wherein said low temperature is lower than -50°C .

21. (New) The process of claim 1, wherein said low temperature is lower than -60°C.

22. (New) The process of claim 1, wherein said substance or substance mixture is substantially insoluble in said suspending medium.

23. (New) The process of claim 1, wherein said fine particulate protein substance or substance mixture is useful for inhalatory therapy.

24. (New) The process of claim 13, wherein said suspending medium is selected from the group consisting of one or more TG227, TG134a, TG152a, ~~and~~ TG143a and mixtures thereof.